

(a) obtaining first and second assay samples containing the analyte, said first and second assay samples being either aliquots of a single sample or contemporaneous samples from the same source;

(b) performing a first specific binding assay on the first assay sample by reacting the first assay sample with a first binding agent to form a first binding agent/analyte complex, and then subsequently reacting the first binding agent/analyte complex with a second binding agent to form a first binding agent/analyte/second binding agent complex;

(c) performing a second specific binding assay on the second assay sample by reacting the second assay sample substantially simultaneously with the first binding agent and the second binding agent to form a first binding agent/analyte/second binding agent complex;

(d) determining the amount of first binding agent/analyte/second binding agent complex formed in the first specific binding assay and the second specific binding assay; and

(e) comparing the amount of first binding agent/analyte/second binding agent complex formed in the first specific binding assay and the second specific binding assay, wherein at least one of the first and second binding agents has a different specificity for the forms of the analyte, whereby the amount of first binding agent/analyte/second binding agent complex formed in the first and second specific binding assays differs depending on the state of the analyte in the sample.

Rule 1.126
²20. (new) The method of claim ²¹19, wherein each of the first and second binding reagents have a different specificity for the forms of the analyte.

³21. (new) The method of claim ²²20, further comprising the step of calculating a combined test result, expressed as a ratio of the amounts of first binding agent/analyte/second binding agent complex formed in the first and second specific binding assays.

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⁴22. (new) The method of claim ²³21, further comprising the step of comparing the combined test result to a standard ratio representative of the first or second state to determine in which state the sample exists.

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23. (new) The method of claim ²⁴~~22~~, wherein the analyte is a gonadotrophin.

⁶
24. (new) The method of claim ²⁵~~23~~, wherein the analyte is follicle stimulating hormone.

⁷
25. (new) The method of claim ²²~~20~~, wherein the analyte is a gonadotrophin.

⁸
26. (new) The method of claim ²⁷~~25~~, wherein the analyte is follicle stimulating hormone.

⁹
27. (new) The method of claim ²¹~~19~~, further comprising the step of calculating a combined test result, expressed as a ratio of the amounts of first binding agent/analyte/second binding agent complex formed in the first and second specific binding assays.

³⁰
28. (new) The method of claim ²⁹~~27~~, further comprising the step of comparing the combined test result to a standard ratio representative of the first or second state to determine in which state the sample exists.

³¹
29. (new) The method of claim ³⁰~~28~~, wherein the analyte is a gonadotrophin.

²
30. (new) The method of claim ³¹~~29~~, wherein the analyte is follicle stimulating hormone.

³
31. (new) The method of claim ²¹~~19~~, wherein the analyte is a gonadotrophin.

⁴
32. (new) The method of claim ³³~~31~~, wherein the analyte is follicle stimulating hormone.

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33. (new) The method according to claim ²¹~~19~~, wherein the first and second specific binding agents are antibodies.

6.
34. (new) The method according to claim ~~33~~³⁵, wherein each binding agent is a monoclonal antibody.

7.
35. (new) The method of claim ~~33~~³⁵, wherein each of the first and second binding reagents have a different specificity for the forms of the analyte.

8.
36. (new) The method of claim ~~35~~³⁷, further comprising the step of calculating a combined test result, expressed as a ratio of the amounts of first binding agent/analyte/second binding agent complex formed in the first and second specific binding assays.

9.
37. (new) The method of claim ~~36~~³⁸, further comprising the step of comparing the combined test result to a standard ratio representative of the first or second state to determine in which state the sample exists.

40.
38. (new) The method of claim ~~37~~³⁹, wherein the analyte is a gonadotrophin.

41.
39. (new) The method of claim ~~38~~⁴⁰, wherein the analyte is follicle stimulating hormone.

2.
40. (new) The method of claim ~~39~~³⁵, wherein the analyte is a gonadotrophin.

3.
41. (new) The method of claim ~~40~~⁴², wherein the analyte is follicle stimulating hormone.

4.
42. (new) The method of claim ~~19~~²¹, wherein in the first specific binding assay, the sample is incubated with a solid phase on which is immobilized the first binding agent, and thereafter, following removal of unbound analyte, the solid phase is incubated with the second binding agent.

5.
43. (new) The method of claim ~~42~~⁴⁴, wherein in the second specific binding assay, the sample is substantially simultaneously incubated with a solid phase to which the first binding reagent is immobilized and with the second binding agent in solution or suspension.

6.
44. (new) The method of claim ~~19~~²¹, wherein in the second specific binding assay, the sample is substantially simultaneously incubated with a solid phase to which the first binding reagent is immobilized and with the second binding agent in solution or suspension.

7.
45. (new) The method of claim ~~19~~²¹, wherein the first or second binding agent is labeled with a label selected from the group consisting of enzymes, fluorescent labels, radiolabels and direct particulate labels.

8.
46. (new) The method of claim ~~19~~²¹, wherein one of the first or second binding agents comprises an anti-FSH antibody expressed by hybridoma cell line ECACC 00032004.

9.
47. (new) The method of claim ~~19~~²¹, wherein one of the first or second binding agents comprises an anti-FSH antibody expressed by hybridoma cell line ECACC 00032005.

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48. (new) The method of claim ~~19~~²¹, wherein one of the first or second binding agents comprises an anti-FSH antibody expressed by hybridoma cell line ECACC 00032004 and the other comprises an anti-FSH antibody expressed by hybridoma cell line ECACC 00032005.

51.
49. (new) A method for evaluating first and second assay samples obtained from a female subject to determine if the subject is in first state in which the subject is in a present or impending fertile condition or a second state in which the subject is in a present or impending infertile condition, comprising evaluating the first and second assay samples in accordance with the method of claim ~~19~~²¹, wherein the difference between the amounts of first binding agent/analyte/second binding agent complex formed in the first and second specific binding assays is indicative of the state of fertility of the female subject.